REMARKS

Claims 1-4, 7-8, 14, and 23 are pending. Claim 8 is cancelled, claims 1-2, 7, 14 and 23 are amended herein. Support can be found for the present claim amendments throughout the original specification and claims and no new matter is believed to have been added by their introduction. For example, amended claims 7 and 23 are supported on page 19, lines 30-36 and continued on page 20, lines 1-27; page 21, lines 12-18; page 27, lines 4-8 and 16-19; and page 40, lines 13-34.

Objections to the Drawings

The Office has objected to informalities existing in the drawings. Accordingly, the Applicants have included corrected drawings in accordance with the requirements provided by the draftsperson in a submission filed concurrently with the present amendment.

Objections to the Specification

The Office has objected to the specification at several locations due to the inclusion of informalities related to ATCC deposit information, and the improper inclusion of embedded hyperlinks. The Applicants have updated the specification herein in accordance with the Office's suggestions. For example, the Applicants have included the appropriate ATCC deposit information and have amended the specification to eliminate embedded hyperlinks that are purportedly in violation of MPEP § 608.01. The Applicants believe the present amendments are sufficient; if the Examiner believes that further amendment is required, a telephone call to the undersigned is respectfully requested.

Objections to the Claims

The Office has objected to claims 2-4 as purportedly not further limiting the subject matter of claim 1. Although the Applicants respectfully disagree, claim 2 is amended herein to recite that the claimed protein consists of the sequence of SEQ ID NO:2. Claims 3-4 depend from amended claim 2. Accordingly, the basis for this rejection is rendered moot. Withdrawal is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph - Written Description

Claims 1-4, 7, 8, 14 and 23 stand rejected under 35 U.S.C. § 112, first paragraph as purportedly lacking adequate written description. The Office has specifically indicated that claims 1, 8 and 23 are broadly drawn to "[an] isolated 125P5C8-related protein comprising the sequence of SEQ ID NO:2." Paper No. 15, page 4. Respectfully, present claims 1 and 8 (as previously amended), and claim 23 (as currently amended) are not directed to a 125P5C8-related protein.

Included in these claims is a modest genus of proteins that have substantial homology to SEQ. ID. No.: 2 and have the functional property of being specifically bound by an antibody which specifically binds a protein of SEQ. ID. No.: 2. This genus thus defines a class which is designed to include variants of the disclosed proteins which might occur in individual subjects, but retain the useful properties of SEQ ID No. 2 as described below.

Applicants point out that there can be minor variations between individuals as to the precise amino acid sequence of any particular protein. Applicants submit that they are entitled to a reasonable scope of protection. Attention is called, for example, to Example 14 of the Written Description Guidelines which, by way of illustration, recognizes that a genus limited by an effective functional definition is a satisfactory level of scope. In the Example, an exemplary effective function (catalytic activity) was present where there was a structural limitation of 95% identity. In the present claims, the recited genus is also limited by functionality (the protein is specifically bound by an antibody that specifically binds a protein of SEQ. ID. NO: 2) and a structural limitation (the protein has 90% identity to SEQ ID NO 2 where any substitutions are conservative substitutions). These structural and functional limitations properly correspond to those exemplified in the Guidelines. Accordingly, the current claims are asserted to be fully supported by the specification as filed. Thus, withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph - Written Description

Claims 1-4, 7, 8, 14 and 23 stand rejected under 35 U.S.C. § 112, first paragraph as purportedly lacking enablement. The Office has indicated that claims 1-4, 7, 8, 14 and 23 are "broadly drawn to a 125P5C8 protein that has at least 6-30 amino acids of SEQ ID NO: 2 and a 125P5C8-related protein that comprises at least one conservative substitution." Id. at page 6. The Office has also indicated that the specification is "enabling for the polypeptides having the amino acid sequences of SEQ ID NO: 2, [but] does not reasonably provide enablement for 125P5C8-

related proteins, variants and related proteins that have less [than] 100% sequence identity or with one undefined conservative substitution." Id. at pages 6-7. The Office has further provided that the "specification is enabled for the polynucleotide sequence, SEQ ID NO: 1, but not for polynucleotides that are variants of the said nucleic acid sequence." Id. at page 7.

Thus, the Applicants acknowledge the Office's indication that the polypeptides and polynucleotides as set forth in SEQ ID NOs: 1 & 2 are enabled. The Applicants respectfully traverse in light of the present claim amendments and discussion provided herein.

As provided above, the present claims include a genus of proteins that have substantial homology to SEQ ID NO: 2, and have the functional property of being specifically bound by an antibody which specifically binds a protein of SEQ ID NO: 2. Thus, although the claims are limited to substantially identical proteins to that disclosed in SEQ ID NO.: 2, this range is further limited to proteins which retain functional properties of SEQ ID NO: 2. Accordingly, the Applicants respectfully assert that the present claims are adequately enabled for their entire claimed scope.

Rejection Under 35 U.S.C. § 112, First Paragraph - Written Description/Biological Deposit

Claim 14 stands rejected under 35 U.S.C. § 112, first paragraph as failing to provide "complete evidence either that the claimed biological materials are known or readily available to the public or complete evidence of the deposit of biological materials." *Id.* at page 11. Accordingly, the Applicants verify and certify that the deposit at the American Type Culture Collection (ATCC) designation No. PTA-3137 was made under the terms of the Budapest Treaty and that all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2, 3, 8 and 23 stand rejected under 35 U.S.C. § 112, second paragraph as purportedly indefinite. The Office has indicated that the recitation of "125P5C8-related proteins" in claims 2, 3 and 23 is vague and indefinite. Respectfully, claims 2 and 3 as previously amended, and claim 23, as currently amended, do not recite the disputed phrase. The Applicants assert that the present amendments to claim 23 render the basis for this rejection moot. Thus, withdrawal of this rejection is respectfully requested.

The Office has also indicated that in claim 8 it is unclear what type of immune response is claimed and "which amino acid residues comprise the epitope capable of inducing the response."

Id. at page 14. As claim 8 is canceled herein, the basis for this rejection is rendered moot. Withdrawal is respectfully requested.

The Office has further indicated that claim 23(g) is indefinite under two separate bases. As the Applicants have amended claim 23(g) to remove the disputed phrases it is believed that the bases for the present rejections of claim 23(g) are rendered moot. Withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 101

Claims 1-4, 7, 8, 14 and 23 stand rejected under 35 U.S.C. § 101 as purportedly not supported by a specific, credible, substantial or well established utility. The Office has indicated that "[t]he mere fact that 125P5C8 seems to be overexpressed in malignant prostate, bladder, kidney and colon tissues does not mean that it functions as a diagnostic marker for cancer." The Office further indicates that "the specification does not exemplify the use of any of the said sequences in differential expression in normal prostate tissue versus high risk (potentially diseased) prostate tissue/ prostate cancer tissue . . .." Moreover, the Office provides that "[t]here is no information supporting the use of the listed sequence or related sequences as a specific tumor marker . . .." The Applicants respectfully traverse.

The current claims are directed to isolated 125P5C8 proteins. The Applicants assert that the present disclosure provides the requisite utility for the claimed proteins. *See Utility Examination Guidelines*, 66(4) Fed. Reg. 1092, 1097-99 ("*Guidelines*"). Respectfully, this assertion is supported by the specification and is evidenced by the following discussion as well as the attached Declarations by Mary Faris, Ph.D. (enclosed herewith as Exhibit A) and Karen Jane Meyrick Morrison, Ph.D. (enclosed herewith as Exhibit B). *See Guidelines*, Section II.B.4, 66(4) Fed. Reg. at 1098.

Differential expression of the claimed proteins in cancerous tissues versus normal tissues is not a required element for utility purposes of the present claims. As indicated in the attached Declaration by Mary Faris, Ph.D., usefulness of a particular protein is not dependent on such differential expression. As provided in the Mary Faris Declaration, the expression of particular proteins in normal tissues does not preclude their use as therapeutic targets.

The production of 125P5C8 protein in prostate, bladder, kidney and colon cancer is sufficient to establish that antibodies raised with respect to this protein are useful. That this is the

case is verified by the Declaration of Karen Jane Meyrick Morrison, Ph.D. For example, the application explicitly discloses and supports the use of 125P5C8 as a diagnostic target, thus by use of any number of well known histological methods, one of skill in the field of histological assessment can conclude that a biopsied tissue is malignant, and that the patient from whom the biopsy was obtained has cancer. This is an important diagnostic and/or prognostic outcome from pathology evaluations in medical or scientific settings.

The claimed polypeptides are also useful in view of the phenomena of altered subcellular protein localization in disease states. Alteration of cells from normal to diseased state causes changes in cellular morphology and is often associated with changes in subcellular protein localization/distribution. For example, cell membrane proteins that are expressed in a polarized manner in normal cells can be altered in disease, resulting in distribution of the protein in a non-polar manner over the whole cell surface.

Alteration in the localization/distribution of a protein in the cell, as detected by immunohistochemical methods, can also provide valuable information concerning the favorability of certain treatment modalities. Accordingly, the ability to determine whether alteration of subcellular protein localization occurred for 125P5C8 make the claimed 125P5C8 proteins very useful. *See, e.g.*, Examples 1, 2 and 11. Use of the claimed compositions allows practitioners to make important diagnostic and therapeutic decisions.

In addition, immunohistochemical reagents specific to 125P5C8 are also useful to detect metastases of tumors expressing 125P5C8 when the polypeptide appears in tissues where 125P5C8 is not normally produced. As shown in Figures 6A-C, expression is substantially absent in many tissues and the presence of the polypeptide in these tissues in subjects who, e.g., have been diagnosed with tumors that express 125P5C8 is evidence of metastasis in these individuals.

As only one utility is required to support a claim to a material, and several such utilities have been described, it is submitted that the outstanding rejection should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this preliminary amendment document to **Deposit Account No. 03-1952** referencing docket no. 511582003500. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 11, 2003

Respectfully submitted,

By _____

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